JAN 2 2 2002

K012398

510(K) SUMMARY
Diomed 810 nm Surgical Lasers and EVLT Procedure Kit

This 510(k) summary of safety and effectiveness for the Diomed 810 nm Surgical Lasers and EVLT Procedure Kit is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Diomed, Inc.
Address:	One Dundee Park Suite 5/6 Andover, MA 01810
Contact Person:	Peter Klein Chief Executive Officer
Telephone:	978-475-7771 978-475-8488 (fax)
Preparation Date: (of the Summary)	January, 2002
Device Name:	Diomed 810 nm Surgical Lasers and EVLT Procedure Kit
Common Name:	Surgical Laser: GaAlAs Semiconductor Diode Laser
Classification Name:	Device, Electrosurgical, Cutting & Coagulation & Accessories (see: 21 CFR 878.4400). Product Code: GEI. Panel: 79
Legally marketed predicate device:	VNUS Closure System (K974521, K003092, K982816)
Description of the Device:	Diomed 810 nm Surgical Lasers and EVLT Procedure Kit is a semiconductor diode lasers operating at 810 $\pm$ 20 microns and associated disposables.
Indications for Use:	Diomed 810 nm Surgical Lasers and EVLT Procedure Kit are intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

Comparison to Predicate Device:	The intended use, method of tissue interaction, specifications, clinical technique and clinical results of the Diomed 810 nm Surgical Lasers and EVLT Procedure Kit are the same or very similar to those of the claimed predicate.
Performance Data:	Clinical tests performed by Diomed have demonstrated the substantially equivalent performance of the Diomed 810 nm Surgical Lasers and EVLT Procedure Kit with the predicate device used for substantially equivalent indications.
Conclusion:	Based on the foregoing, Diomed believes that the Diomed 810 nm Surgical Lasers and EVLT Procedure Kit are substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Diomed, Ltd.
c/o Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

Re: K012398
Trade/Device Name: Diomed 810 nm Surgical Lasers and EVLT Procedure Kit
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 22, 2001
Received: October 24, 2001

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K012398

Device Name: Diomed 810 nm Surgical Lasers and EVLT Procedure Kit

Indications For Use:

Diomed 810 nm Surgical Lasers and EVLT Procedure Kit are intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 810.109)

Over-The-Counter Use ___

for Mark N Melkerson
(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K012398